



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/520,506

11/01/2005

Craig A. Townsend

029869.00001-UA01

2647

136 7590 09/24/2008

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

09/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,506	Applicant(s) TOWNSEND ET AL.	
	Examiner TIMOTHY P. THOMAS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 13, 20-25 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 14-19, 26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 6/27/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments with respect to the written description rejection under 35 USC 112, 1st paragraph have been fully considered but they only persuasive in part:

Claims 1-5, 12, and 14-19 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, and therefore both claims 1 and 15 are presumptively described; applicants are not claiming compounds which are characterized by particular functionality. This argument is not persuasive; claim 1 does not recite any compound by its name or structure, with the exception of a group of compounds that are excluded from the subject matter of the claims. The phrases "a compound being able to decrease ATP levels in the microbe...and not kill mammalian cells..." in claim 1, and "a compound [that] produces

Art Unit: 1614

an overexpression of the b-subunit of ATP synthase...” in claim 15 are claims of a group of compounds, without any associated structural features, characterized by one or two particular functionalities. Even though these compounds are recited for claimed methods of treating an infection, the compounds are still part of the claimed subject matter defining the metes and bounds of the claims.

Applicant argues with respect to claims 5, 14, 19 and new claim 28 these claims explicitly set forth the compounds and/or microbially-based infections, which have been described sufficiently. This is persuasive with respect to claim 28 (excluded from the instant rejection), which recites the explicit compounds and microbially-based infections that do have sufficient description, both in the same claim. However, the other claims, which only have description for either compounds or microbial infections, but not both, still contain one of the broad genus claims which do not have sufficient description.

3. Applicant's arguments, see p. 14, 1st paragraph, filed 6/27/2008, with respect to the rejection under 35 USC 102(b) have been fully considered and are persuasive. The rejection of claims 1-3 and 14-17 has been withdrawn.

The rejection is withdrawn due to the claim amendment excluding compound SI-73 from the subject matter of the instant claims.

4. Applicant's arguments with respect to the rejection of claims 1-5, 12, 14-19 and 26 under 35 USC 102(e) have been fully considered but they are not persuasive:

Claims 1-5, 12, 14-19, 26 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuhajda, et al. (US 2006/0247302 A1; priority claim 2002 Jul 9).

The extension of this rejection to claim 28 is necessitated by the claim amendment.

Applicant argues compound VII (Kahajda as Compound 74) was not tested for anti-microbial properties; accordingly Kuhajda does not disclose a method which contains each and every element of the claimed method, either explicitly or inherently. This argument is not persuasive; the required step of administration of an effective amount of a compound to a subject in need of treating a microbially-based infection is taught, as present in the record. The measurement of ATP, as recited in claim 1, is not considered to be a required step of the practice of the method of claim 1; only that the compound "being able to decrease ATP levels...and not kill mammalian cells...", which would be an inherent property of administering the same compound of the instant claims for the same purpose. Since the compound is the same compound as in the instant claims and the same required method steps for the same purpose is taught in the prior art, the compound is considered to inherently possess the ATP decrease without killing the mammalian cells, as disclosed by applicant. Similarly, the requirement of claim 15 that "the compound produces an overexpression of the b-subunit of ATP synthase" is also considered to be an inherent property of administration of the same compound as the instant claims for the same purpose.

As pointed out in the previous Office Action, the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on". Applicants have not met this burden to demonstrate the

Art Unit: 1614

inherent properties are not possessed by the teaching of Kahajda; therefore the rejection is maintained.

Specification

5. The disclosure is objected to because of the following informalities: the amendment to the specification, filed 6/27/2008, describing the content of PCT/US98/17830 discloses the formula $R-SO_x-Z-CO-Y$, but n (not x) is limited to 1 or 2. It is assumed that x in the formula is a typographical error for n .

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 12, 14-19, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is necessitated by the claim amendment. The claim amendment changing Y from $-NH$ to $-NH_2$ is considered new matter for some of the compounds now excluded. The application PCT/US98/17830 (and publication of the application, WO 99/10321), which was identified as providing written support for the amendment discloses compounds with the same general formula as the instant claims exclude, $R-$

Art Unit: 1614

SO_n-Z-CO-Y, however, Z is defined differently in the incorporated-by-reference application from the instant claims; in the prior documents Z is defined as “a radical selected from -CH₂-, -O-, and -NH-, two or three of these radicals coupled together or -CH₂=CH₂-”; in contrast, in the instant claims Z is defined as a hydrocarbon linking moiety that may contain a heteroatom, a broader definition of this moiety including more compounds than the incorporated document cited. Compounds that have Y as -NH₂, where Z is outside of the definition in PCT/US98/17830 but still within the instant claim definition of Z, compounds which are excluded from the subject matter by the claim amendment are New Matter, not sufficiently described at the time of filing the application.

Conclusion

8. No claim is allowed.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 1614

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

Application/Control Number: 10/520,506
Art Unit: 1614

Page 8